DEC 1 9 2000

# Summary of Safety and Effectiveness K002738

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

## 1. Submitters Information

| | |
|---|---|
| Contact person: | William J. Pignato<br>Director of Regulatory Affairs |
| Address: | Bayer Diagnostics Corp.<br>63 North Street<br>Medfield, MA 02052 |
| Phone: | 508 359-3825 |
| Date Summary Prepared: | August 25,2000 |

## 2. Device Information

| | |
|---|---|
| Proprietary Name: | Bayer 400 System |
| Common Name: | Analyzer for Blood Gas, electrolytes and metabolites |
| Classification Name: | Electrode/Sensor measurement of blood gases, blood pH and blood electrolytes |

Classification Number:

| | |
|---|---|
| Calcium - | 21 CFR 862.1145, Class II |
| Chloride - | 21 CFR 862.1170, Class II |
| Glucose - 2 | 1 CFR 862.1345, Class II |
| Hematocrit - | 21 CFR 864.6400, Class II |
| Potassium - | 21 CFR 862.1600, Class II |
| Sodium - | 21 CFR 862.1665, Class II |
| *p*CO2 - | 21 CFR 862.1120, Class II |
| *p*O2 - | 21 CFR 862.1120, Class II |
| pH - | 21 CFR 862.1120, Class II |

## 3. Predicate Device Information

| | 1 | 2 |
|---|---|---|
| Name: | Rapidpoint 400 | Model 865 Analyzer |
| Manufacturer: | Bayer Diagnostics Corp. | Bayer Diagnostics Corp. |
| 510(k) Number: | DC# K961657 | D.C. # K946206 |

## 4. Device Description

The 400 Series system analyzer is a point of care and laboratory testing analyzer used to for the direct measure of whole blood samples for the determination of the following parameters:

- partial pressures of carbon dioxide; $pCO_2$
- partial pressure of oxygen $pO_2$
- pH
- sodium; $Na^+$
- potassium; $K^+$
- ionized calcium; $Ca^{++}$
- chloride; $Cl^-$
- glucose
- hematocrit; Hct

## 5. Statement of Intended Use

The Bayer 400 System is intended for the point-of-care and laboratory testing of blood gases, electrolytes and metabolites in arterial, venous and capillary whole blood samples.

## 6. Summary of Technological Characteristics

The 400 Series System uses measurement technology that is based on electrochemical phenomena. The device use potentiometry, amperometry and conductimetric methods to convert the potential generated by the sensor to an electrical signal which the system then converts to a value that represents that concentration of a specific analyte in the whole blood sample.

The 400 Series sensors (i.e., electrodes) provide direct measurement of the specific analytes or substances in the sample. Each sensor in the 400 system is highly selective for one substance over others.

The sensors employ the use of thick-film hybrid technology and a solid-state design in place of the traditional electrodes that use internal fill solutions that are used in the traditional blood gas/electrolyte systems.

Features of the planar-format sensors include:

- Suitability for use with the compact disposable measurement cartridge used with the 400 Series
- Sensors require a small volume of sample (75 uL)
- Sensors are maintenance free

The sensors use the following measurement technology:

| ***Sensor*** | ***Measurement Technology*** |
|---|---|
| | |
| pH, Na+, K+, Ca++, Cl- | potentiometric method using ion-selective electrode technology |
| reference | silver electrode in potassium chloride and silver chloride |
| pCO2 | potentiometric method |
| p02 | amperometric method |
| glucose | amperometric method using an enzyme electrode that uses glucose oxidase |
| hematocrit | conductimetic method |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 9 2000

Mr. William Pignato
Director of Regulatory Affairs
Bayer Corporation
Business Group Diagnostics
63 North Street
Medfield, Massachusetts 02052-1688

Re: K002738
Trade Name: Bayer Rapidpoint 400 System
Regulatory Class: II
Product Code: CHL, JFP, CGZ, CGA, CEM, JGS, GKF
Dated: November 13, 2000
Received: November 15, 2000

Dear Mr. Pignato:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002738

Device Name: Bayer Rapidpoint 400 System

Indications for Use:

The 400 system is designed to provide the determination in whole blood the following parameters:

- partial pressure of carbon dioxide
- partial pressure of oxygen
- pH
- sodium
- potassium
- ionized calcium
- chloride
- glucose
- hematocrit

Sean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002738

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)